

## REMARKS

Claims 1 – 46 were cancelled prior to examination.

Claims 47 - 67 were pending prior to this Amendment.

New claims 68 – 71 have been added.

The new method claim 69 corresponds to the pending device claim 47 and is directed to the same inventive concept. New dependent method claims 70 and 71 correspond to the pending device claims 56 (or 57) and 64 (or 65 – 67).

In the Office Action of July 3, 2006, the Examiner objected to an informality in the specification. Applicant amended the corresponding part of the specification. The Examiner also objected to claims 48, 50, 56, 59, 62, and 65 – 67, which were amended above.

The Examiner rejected claim 47 - 67 under the judicially created doctrine of obviousness-type double patenting over claims 1-49 of US Patent 6,618,614; over claims 1-46 of US Patent 6,526,309; and over claims 1-20 of US Patent 5,987,351. Applicant respectfully disagrees with these rejections.

Applicant respectfully submits that the Examiner did not meet the required *prima facie* burden when making the above rejections. Specifically, MPEP §804 states:

A double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103" except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Applicant respectfully submits that the Examiner did not make properly the obviousness determination as required by MPEP §804:

Since the analysis employed in an obviousness-type double patenting determination parallels the guidelines for a 35 U.S.C. 103(a) rejection, the factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103 are employed when making an obvious-type double patenting analysis. These factual inquiries are summarized as follows:

- (A) Determine the scope and content of a patent claim relative to a claim in the application at issue;
- (B) Determine the differences between the scope and content of the patent claim as determined in (A) and the claim in the application at issue;
- (C) Determine the level of ordinary skill in the pertinent art; and
- (D) Evaluate any objective indicia of nonobviousness.

The conclusion of obviousness-type double patenting is made in light of these factual determinations.

Any obviousness-type double patenting rejection should make clear:

- (A) The differences between the inventions defined by the conflicting claims - a claim in the patent compared to a claim in the application; and
- (B) The reasons why a person of ordinary skill in the art would conclude that the invention defined in the claim at issue would have been an obvious variation of the invention defined in a claim in the patent.

Therefore, Applicant respectfully submits that, to make properly the *prima facie* rejection under the obviousness-type double patenting doctrine, the Examiner has to satisfy the above requirements. That is, the above requires obviousness determination with respect to the prior patent claims only (and, of course, not the teaching in the specification which is not prior art). Regarding the obviousness determination, the Federal Circuit has stated numerous times the criteria for rejecting a claim under 35 U.S.C. §103 as being obvious. In the above obviousness rejections, Applicant respectfully submits that the Examiner did not follow the law when making the above rejections. For example, as stated in In re Fritch:

In proceedings before the Patent and Trademark Office, the Examiner bears the burden of establishing a *prima facie* case of obviousness based upon the prior art. *In re Piasecki*, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984). A[The Examiner] can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988) (citing *In re Lalu*, 747 F.2d 703, 705, 223 USPQ 1257, 1258 (Fed. Cir. 1988)). The patent applicant may then attack the Examiner's *prima facie* determination as improperly made out, or the applicant may present objective evidence tending to support a conclusion of nonobviousness. *In re Heldt*, 433 F.2d 808, 811, 167 USPQ 676, 678 (CCPA 1970).

In re Fritch, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992)

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination. Under section 103, teachings of references can be combined *only* if there is some suggestion or incentive to do so. *ACS Hosp. Systems, Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984) Although couched in terms of combining teachings found in the prior art, the same inquiry must be carried out in the context of a purported obvious modification of the prior art. The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *In re Gordon*, 733 F.2d at 902, 221 USPQ at 1127. In re Fritch, 23 USPQ2d 1780, 1783 (Fed. Cir. 1992), emphasis ours.

In the present case, the Examiner has not specifically shown how the cited claims may be modified to arrive at the invention claimed in the present application. Applicant respectfully submits that the Examiner failed to establish the *prima facie* case of obviousness as explained below:

The Examiner did not establish the *prima facie* case of obviousness, as required by the case law and specifically mandated by the Manual of Patent Examining Procedure (MPEP) §2143:

#### **2143 Basic Requirements of a Prima Facie Case of Obviousness [R-1]**

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. MPEP §2143

Applicant respectfully submits that the Examiner did not meet the tree criteria necessary to establish the *prima facie* case of obviousness. Regarding any statements, The Examiner is required to provide evidence supporting such statement, as stated in 37 CFR §1.104(d)(2):

When a rejection in an application is based on facts within the personal knowledge of an employee of the Office, the data shall be as specific as possible,

and the reference must be supported, when called for by the applicant, by the affidavit of such employee, and such affidavit is subject to contradiction or explanation by the affidavits of the applicant and other persons. 37 CFR §1.104(d)(2) (emphasis ours)

The pending claims are non-obvious with respect to the cited claims 1-49 of US Patent 6,618,614; and non-obvious with respect to the cited claims 1-46 of US Patent 6,526,309; and non-obvious with respect to the cited claims 1-20 of US Patent 5,987,351.

Device claim 47 or the method claim 69 include several novel features. The novel optical examination device, for *in vivo* tissue examination, utilizes optical fibers having arrayed proximal ends for transmitting light to and from the examined biological tissue. The optical examination device includes an optical source for emitting light in the visible to infrared range, an optical detector for detecting light; and a controller. The array of optical fibers includes end portions freely protruding from a support and arranged for engaging the scalp or skin of a subject at distal ends of the fibers. The optical fibers include proximal ends arrayed for coupling light from the light source into source fibers and for coupling light from detector fibers into the optical detector by indexing in space fiber locations with respect to tissue positions corresponding to the distal ends engaging the scalp or skin of the examined subject. The controller is constructed and arranged to control operation of the light source and the optical detector and control introduction and detection of light at the arrayed proximal ends. Applicant respectfully submit that all of the above claim elements are not recited in the cited claims of the Applicants patents and are non-obvious with respect to the cited claims.

In summary, all pending claims 47 – 71 are now in condition for allowance. Accordingly, this application is in condition for allowance and such action is respectfully requested. Should there be any outstanding issue left, the Examiner is respectfully invited to call the undersigned at the telephone number provided below.

Please apply any PTO fees or any credits to Deposit Account 50-2196.

Respectfully submitted,



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Ivan D. Zitkovsky